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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

KIMBERLY M. ROBINSON, individually,  
as next of kin of and as representative  
of the Estate of DORIS J. ELLIOTT,  
deceased,

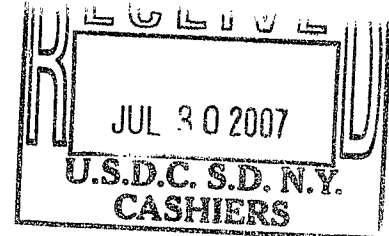
Plaintiff,

Civil Action No.: \_\_\_\_\_

vs.

MERCK & CO., INC.,

Defendant.



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**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Kimberly M. Robinson, as next of kin of and representative of the Estate of Doris J. Elliott, deceased, through her undersigned attorneys Levin, Papantonio et al., sues Defendant Merck & Company, Inc., and alleges as follows:

**I. JURISDICTION AND VENUE**

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State Kentucky, and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be filed directly in the Southern District of New York.

## II. PARTIES

3. Doris J. Elliott was born on October 13, 1929. At all relevant times Ms. Elliott was a resident of the State of Kentucky, and used FOSAMAX from approximately March 2002 until June 2006. Plaintiff is a citizen of the State of Kentucky and is the surviving daughter of Ms. Elliott. Ms. Elliott died and left three children, Plaintiff, Karen J. Mansfield, and Karla D. Kirk. Plaintiff is the Independent Executrix of the Estate as adjudicated in the Commonwealth of Kentucky Fayette District Court, Division I, in the State of Kentucky. In addition to her own individual interest, Plaintiff represents the interests of the Estate of Doris J. Elliott, and the interest of the other surviving heirs, Karen J. Mansfield and Karla D. Kirk. Plaintiff brings this action to recover damages for personal injuries sustained by decedent, Doris J. Elliott, after taking FOSAMAX.
4. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.
5. Defendant was at all relevant times authorized to conduct business in the State of Kentucky.
6. At all times relevant Defendant regularly transacted business in the State of Kentucky and continues to do so.

7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.
8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Kentucky for the treatment or prevention of osteoporosis, Paget's Disease and other off-label uses.
9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Kentucky.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Kentucky.

### **III. SUMMARY OF THE CASE**

11. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.
12. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Ms. Elliott, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.

13. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Decedent Doris J. Elliott, other consumers, and the medical community.
14. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
15. As a result of Defendant's actions and inaction, Ms. Elliott was injured due to her ingestion of FOSAMAX. Plaintiff accordingly seeks compensatory damages.

#### **IV. FACTUAL BACKGROUND**

16. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
17. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.
18. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
19. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and

alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

20. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).
21. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
22. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turning into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

23. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.
24. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.
25. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.
26. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
27. Since FOSAMAX was released, the FDA has received a number of reports of osteonecrosis of the jaw among users of FOSAMAX.
28. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

29. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.
30. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.
31. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.
32. FOSAMAX is one of Defendant's top selling drugs. Averaging more than \$3 billion a year in sales.
33. Consumers, including Ms. Doris J. Elliott, who have used FOSAMAX for treatment or prevention of osteoporosis, Paget's Disease and/or other off-label uses, have several alternative safer products available to treat their conditions.
34. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Doris J. Elliott, or the medical community, of such risks.
35. As a direct result, Ms. Elliott was prescribed FOSAMAX and was permanently and severely injured, having suffered serious consequences from the ingestion of

FOSAMAX. Until her death, Ms. Elliott required extensive ongoing medical care and treatment as a result of these injuries.

36. Ms. Elliott suffered from mental anguish from the knowledge that she would have life-long complications as a result of the injuries she sustained from the use of FOSAMAX.
37. Ms. Elliott was prescribed and began taking FOSAMAX in March 2002.
38. Ms. Elliott used FOSAMAX as prescribed and in a foreseeable manner.
39. As a direct and proximate result of using FOSAMAX, Ms. Elliott suffered severe personal injury to the jaw.
40. Ms. Elliott, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and permanent injuries and emotional distress.
41. Ms. Elliott used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
42. Ms. Elliott would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Ms. Elliott would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.
43. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Ms. Elliott and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has

been tolled by reason of Defendant's fraudulent concealment.

44. As a result of Defendant's actions, Ms. Elliott and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Ms. Elliott had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

## V. COUNTS

### COUNT I: NEGLIGENCE

45. Plaintiff re-alleges the above as if fully set forth herein.
46. Defendant owed Ms. Elliott, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
47. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:
- a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;
  - b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;
  - c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
  - d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Ms. Elliott, without an adequate warning of the

significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

48. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Ms. Elliott sustained significant and permanent injury of the jaw.

In addition, Ms. Elliott required extensive healthcare and services and she incurred medical and related expenses. As a result, Ms. Elliott also suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies.

49. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### COUNT II: STRICT LIABILITY

50. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

51. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Ms.

Elliott.

52. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
53. Ms. Elliott used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.
54. FOSAMAX failed to perform safely when used by ordinary consumers, including Ms. Elliott, including when it was used as intended and in a reasonably foreseeable manner.
55. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
56. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.
57. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Ms. Elliott, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.
58. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as

to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

59. Ms. Elliott and her physicians could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

60. As a direct and proximate consequence of Defendant's conduct, Ms. Elliott sustained significant and permanent injury of the jaw. In addition, Ms. Elliott required extensive healthcare. Ms. Elliott and her estate incurred medical and related expenses. Ms. Elliott also suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Ms. Elliott incurred mental and physical pain and suffering.

61. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

### COUNT III: BREACH OF EXPRESS WARRANTY

62. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

63. Defendant expressly represented to Ms. Elliott, her physicians, other consumers and

the medical community that FOSAMAX was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

64. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

65. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

66. Ms. Elliott, her physicians, other consumers, and the medical community relied upon Defendant's express warranties.

67. As a direct and proximate consequence of Defendant's actions, Ms. Elliott sustained serious significant and permanent injury to her jaw. In addition, she required extensive healthcare and incurred medical and related expenses as a result. Ms. Elliott also suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Ms. Elliott incurred mental and physical pain and suffering.

68. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive

damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

69. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
70. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.
71. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
72. Defendant was aware that consumers, including Ms. Elliott, would use FOSAMAX for treatment or prevention of osteoporosis or Paget's Disease and for other off-label purposes.
73. Ms. Elliott, her physicians, and the medical community, reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.
74. Defendant breached its implied warranty to consumers, including Ms. Elliott; FOSAMAX was not of merchantable quality or safe and fit for its intended use.
75. Consumers, including Ms. Elliott, her physicians, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.
76. FOSAMAX reached consumers including Ms. Elliott without substantial change in the condition in which it was manufactured and sold by Defendant.
77. As a direct and proximate result of Defendant's action, Ms. Elliott sustained significant and permanent injury of the jaw. In addition, Ms. Elliott required

extensive healthcare and incurred medical and related expenses as a result. Ms. Elliott also suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Ms. Elliott incurred mental and physical pain and suffering.

78. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

79. Plaintiff re-alleges the above paragraphs as if fully set forth herein.

80. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and Paget's Disease; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

81. Defendant knew that its representations were false, yet it willfully, wantonly, and

recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Ms. Elliott, her physicians and the medical community.

82. The representations were made by Defendant with the intent that doctors and patients, including Ms. Elliott and her physicians, rely upon them.

83. Defendant's representations were made with the intent of defrauding and deceiving Ms. Elliott, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

84. Ms. Elliott, her physicians and others relied upon the representations.

85. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Ms. Elliott.

86. As a direct and proximate result, Ms. Elliott sustained significant and permanent injury to her jaw. In addition, as a result of her injury, Ms. Elliott required extensive healthcare and incurred medical and related expenses as a result. Ms. Elliott also suffered diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Ms. Elliott incurred mental and physical pain and suffering.

87. Defendant's conduct as described above was committed with knowing, conscious,

wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

88. Plaintiff re-alleges the above paragraphs as if fully set forth herein.
89. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:
  - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and
  - b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.
90. Defendant had sole access to material facts concerning the dangers and unreasonable risks associated with FOSAMAX.
91. Defendant's concealment of information about the risks associated with taking FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.
92. The concealment of information and the misrepresentations about FOSAMAX were

made by Defendant with the intent that doctors and patients, including Ms. Elliott and her physicians, rely upon them.

93. Ms. Elliott, her doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks associated with taking FOSAMAX that Defendant had concealed from them.

94. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations, Ms. Elliott suffered significant and permanent injury to her jaw as well as severe and permanent injuries, including pain, mental and physical anguish and suffering, a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff and her estate incurred expenses for medical care and treatment due to the injuries caused by FOSAMAX.

95. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Ms. Elliott, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

#### VI. GLOBAL PRAYER FOR RELIEF

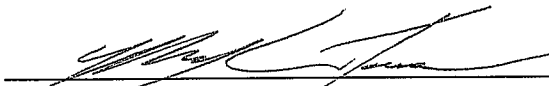
WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;

- c. reasonable attorneys' fees where recoverable;
- d. costs of this action; and
- e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and issues so triable.



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